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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

VALEANT PHARMACEUTICALS INTERNATIONAL, INC., SALIX PHARMACEUTICALS, INC., PROGENICS PHARMACEUTICALS, INC., and WYETH LLC, Plaintiffs, v. MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LIMITED, and MYLAN INC., Defendants.	Civil Action No. 17-6714(SRC)(CLW) *Document Filed Electronically*

DEFENDANTS' ANSWER TO PLAINTIFFS' AMENDED COMPLAINT AND SEPARATE DEFENSES

Defendants Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, and Mylan Inc. (collectively, "Defendants"), by and through their counsel, hereby answer the First Amended Complaint (ECF No. 7) of Plaintiffs Valeant Pharmaceuticals International, Inc., Salix Pharmaceuticals, Inc., Progenics Pharmaceuticals, Inc., and Wyeth LLC (collectively, "Plaintiffs"), and assert their separate defenses as follows:

THE PARTIES

1. Plaintiff Valeant is a corporation organized and existing under the laws of Canada. Its United States headquarters are located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 1, and therefore deny them.

2. Plaintiff Salix is a corporation organized and existing under the laws of California, having its principal place of business at 8510 Colonnade Center Drive, Raleigh, North Carolina 27615. Salix is the registered holder of approved New Drug Application No. 021964, which covers subcutaneous Relistor®.

ANSWER: Upon information and belief, Defendants admit that Food and Drug Administration ("FDA") public records indicate that Salix Pharmaceuticals, Inc. ("Salix") is the holder of New Drug Application ("NDA") No. 021964 for methylnaltrexone bromide injection, for subcutaneous use, 8 mg/0.4 mL and 12 mg/0.6 mL pre-filled syringes and 12 mg/0.6 mL single-dose vial, marketed under the trade name Relistor®. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 2, and therefore deny them.

3. Plaintiff Progenics is a corporation organized and existing under the laws of Delaware, having its principal place of business at One World Trade Center, 47th Floor, New York, New York 10007.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 3, and therefore deny them.

4. Plaintiff Wyeth LLC, formerly Wyeth, is a Delaware LLC, having places of business at 235 East 42nd Street, New York, New York 10017, and One Giralda Farms, Madison, New Jersey 07940.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 4, and therefore deny them.

5. Upon information and belief, Defendant Mylan Pharmaceuticals is a corporation organized and existing under the laws of West Virginia, having a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Upon information and belief, Mylan Pharmaceuticals is a wholly-owned subsidiary of Mylan Inc. and an agent or affiliate of Mylan Labs.

ANSWER: Defendants admit that Mylan Pharmaceuticals Inc. ("MPI") is a corporation organized and existing under the laws of West Virginia and has a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Defendants further admit that MPI is a wholly-owned subsidiary of Mylan Inc. Defendants deny any remaining allegations in paragraph 5.

6. Upon information and belief, Defendant Mylan Labs is a corporation organized and existing under the laws of India, having a place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills 500034, Hyderabad, India. Upon information and belief, Mylan Labs is a wholly-owned subsidiary of Mylan Inc. and an agent or affiliate of Mylan Pharmaceuticals.

ANSWER: Defendants admit that Mylan Laboratories Limited ("MLL") is an entity organized and existing under the laws of India and has a place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills 500034, Hyderabad, India. Defendants further admit that MLL is a wholly-owned subsidiary of Mylan Inc. Defendants deny any remaining allegations in paragraph 6.

7. Upon information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a place of business at 1000 Mylan Blvd., Canonsburg, Pennsylvania 15317.

ANSWER: Admitted.

NATURE OF THE ACTION

8. This is an action for infringement of United States Patent Nos. 9,669,096 ("the '096 patent") and 9,492,445 ("the '445 patent") arising under the United States patent laws, Title 35, United States Code, § 100 *et seq.*, including 35 U.S.C. §§ 271 and 281, and for declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202. This action relates to Mylan's filing of an Abbreviated New Drug Applications ("ANDA") [sic] under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market its generic methylnaltrexone bromide formulations for subcutaneous injection, 12 mg/0.6 mL single-use vial ("Mylan's generic methylnaltrexone vial product") and 8 mg/0.4 mL and 12 mg/0.6 mL pre-filled syringes ("Mylan's generic methylnaltrexone pre-filled syringe products") (collectively "Mylan's generic methylnaltrexone injectable products").

ANSWER: Paragraph 8 contains legal conclusions to which no response is required. To the extent a response is required, Defendants admit that the Amended Complaint purports to state claims for infringement of United States Patent Nos. 9,669,096 ("the '096 patent") and 9,492,445 ("the '445 patent") arising under the United States patent laws, Title 35, United States Code, § 100 *et seq.*, but denies that 35 U.S.C. §§ 271(a), (b), (c), and/or (g) is applicable. Defendants further admit that MLL, as the sole applicant, submitted to the FDA an Abbreviated New Drug Application ("ANDA") seeking approval for MLL's proposed methylnaltrexone bromide injection, for subcutaneous use, 12 mg/0.6 mL single-dose vial. Defendants further admit that MLL, as the sole applicant, submitted to the FDA an ANDA seeking approval for MLL's proposed methylnaltrexone bromide injection, for subcutaneous use, 12 mg/0.6 mL and 8 mg/0.4 mL single-dose pre-filled syringes. Defendants deny that the Amended Complaint states proper claims for infringement of the '096 and '445 patents and/or that such claims have any merit. Defendants deny any remaining allegations in paragraph 8.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent a response is required, Defendants deny that this Court has subject matter jurisdiction over any purported claim in Plaintiffs' Amended Complaint against Defendants alleging infringement under 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

10. Upon information and belief, this court has jurisdiction over Mylan Pharmaceuticals. Upon information and belief, Mylan Pharmaceuticals is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Mylan Pharmaceuticals directly, or indirectly, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Mylan's generic methylnaltrexone injectable products. Upon information and belief Mylan Pharmaceuticals is registered to do business in New Jersey and purposefully has conducted and continues to conduct business in this judicial district.

ANSWER: Paragraph 10 contains legal conclusions to which no answer is required. To the extent a response is required, denied. Defendants aver that MPI is not subject to personal jurisdiction in this Court.

11. Upon information and belief, this court has jurisdiction over Mylan Labs. Upon information and belief, Mylan Labs is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Mylan Labs directly, or indirectly, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Mylan's generic methylnaltrexone injectable products. Upon information and belief Mylan Labs purposefully has conducted and continues to conduct business in this judicial district.

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Defendants aver that MLL is not subject to personal jurisdiction in this Court.

12. Upon information and belief, this court has jurisdiction over Mylan Inc. Upon information and belief, Mylan Inc. is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief,

Mylan Inc. directly, or indirectly, manufactures, markets, and sells generic drug products, including generic products manufactured by Mylan Pharmaceuticals and/or Mylan Labs, throughout the United States and in this judicial district, and this judicial district is a likely destination for Mylan's generic methylnaltrexone injectable products. Upon information and belief Mylan Inc. is registered to do business in New Jersey and purposefully has conducted and continues to conduct business in this judicial district.

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Defendants aver that Mylan Inc. is not subject to personal jurisdiction in this Court.

13. Upon information and belief, Mylan Pharmaceuticals is registered to do business in New Jersey under business ID 0100214277, is registered as a drug manufacturer and wholesale drug distributer under registration number 5003762, and has appointed Corporation Service Company, 830 Bear Tavern Road, West Trenton, NJ 08628, as its registered agent for the receipt of process.

ANSWER: Defendants admit that MPI is a registered business entity in the State of New Jersey. Defendants deny any remaining allegations in paragraph 13.

14. Upon information and belief, Mylan Inc. is registered to do business in New Jersey under business ID 010097192 and has appointed Corporation Service Company, 830 Bear Tavern Road, West Trenton, NJ 08628, as its registered agent for the receipt of process.

ANSWER: Defendants admit that Mylan Inc. is a registered business entity in the State of New Jersey. Defendants deny any remaining allegations in paragraph 14.

15. Mylan's ANDA Nos. 208592 and 208594 are the subject of an on-going infringement litigation in the District of New Jersey: *Valeant Pharmaceuticals et al. v. Mylan Pharmaceuticals Inc., et al.*, Civil Action No. 2:15-cv-08180 (consolidated).

ANSWER: Defendants admit that Plaintiffs brought the actions styled *Valeant Pharmaceuticals et al. v. Mylan Pharmaceuticals Inc., et al.*, Civil Action Nos. 2:15-08180 and 2:16-00035 against Defendants in the District of New Jersey, and that Plaintiffs' complaints in those actions purport to state claims of patent infringement against Defendants related to MLL's ANDA Nos. 208592 and 208594. Defendants further admit that Civil Action Nos. 2:15-08180 and 2:16-00035 are consolidated for all purposes under the case caption Civil Action No. 2:15-

08180(SRC)(CLW) (consolidated). Defendants deny that Plaintiffs' claims of infringement in Civil Action No. 2:15-08180(SRC)(CLW) (consolidated) are proper and/or have any merit. Defendants deny any remaining allegations in Paragraph 15.

16. Mylan Pharmaceuticals and Mylan Inc. avail themselves of the rights, benefits, and privileges of this Court by filing complaints in the District of New Jersey: *Mylan Pharmaceuticals, Inc. v. Celgene Corporations*, Civil Action No. 2:14-cv-02094; and *Mylan Inc. et al. v. Apotex Inc. et al.*, Civil Action No. 3:14-cv-04560.

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that MPI and/or Mylan Inc. have previously filed a complaint in the District of New Jersey. Defendants deny any remaining allegations in paragraph 16.

17. Mylan Pharmaceuticals, Mylan Labs, and Mylan Inc. consented to or did not contest the jurisdiction of this Court in at least the following District of New Jersey actions: *Baxter Healthcare Corp. et al. v. Agila Specialties Private Limited et al.*, Civil Action No. 1:14- cv-07094 (Mylan Pharmaceutical and Mylan Labs); *Horizon Pharma, Inc., et al. v. Mylan Pharmaceuticals Inc., et al.*, Civil Action No. 3:15-cv-03327 (Mylan Pharmaceuticals, Mylan Labs, and Mylan Inc.); *Astrazeneca AB et al. v. Mylan Pharmaceuticals Inc. et al.*, Civil Action No. 3:13-cv-04022 (Mylan Pharmaceuticals, Mylan Labs, and Mylan Inc.); and *Janssen Products, L.P. et al. v. Lupin Limited et al.*, Civil Action No. 2:10-cv-05954 (Mylan Pharmaceuticals and Mylan Inc.).

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that to conserve the resources of the parties and the Court, and under the particular circumstances surrounding those actions, MPI, MLL, and/or Mylan Inc. did not contest personal jurisdiction for the limited purposes of Civil Action Nos. 3:13-cv-04022 and 2:10-cv-05954 only. Defendants deny any remaining allegations in paragraph 17. Defendants aver that they are not subject to personal jurisdiction in this Court.

18. Mylan Pharmaceuticals, Mylan Labs, and Mylan Inc. availed themselves of the rights, benefits, and privileges of this Court by asserting counterclaims in at least the following prior District of New Jersey actions: *Baxter Healthcare Corp. et al. v. Agila Specialties Private Limited et al.*, Civil Action No. 1:14-cv-07094 (Mylan Pharmaceuticals and Mylan Labs); *Horizon Pharma, Inc., et al. v. Mylan Pharmaceuticals Inc., et al.*, Civil Action No. 3:15-cv-03327 (Mylan Pharmaceuticals, Mylan Labs, and Mylan Inc.); *Astrazeneca AB et al. v. Mylan Pharmaceuticals Inc. et al.*, Civil Action No. 3:13-cv-04022 (Mylan Pharmaceuticals, Mylan Labs, and Mylan Inc.);

and *Janssen Products, L.P. et al. v. Lupin Limited et al.*, Civil Action No. 2:10-cv-05954 (Mylan Pharmaceuticals and Mylan Inc.).

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that MPI, MLL, and/or Mylan Inc. have before asserted counterclaim(s) in the District of New Jersey in response to Plaintiff's claims asserted in a case filed there. Defendants deny any remaining allegations in paragraph 18. Defendants aver that they are not subject to personal jurisdiction in this Court.

19. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny that venue is proper in the District of New Jersey.

20. Mylan Pharmaceuticals, Mylan Labs, and Mylan Inc. did not contest venue in this judicial district in at least the following actions: *Sanofi-Aventis U.S. LLC, et al. v. Mylan Laboratories Ltd.*, Civil Action No. 3:15-cv-3392 (Mylan Labs); *Astrazeneca AB et al. v. Mylan Laboratories Limited et al.*, Civil Action No. 3:12-cv-01378 (Mylan Labs, Mylan Inc.); *Ortho-McNeil-Janssen Pharmaceuticals, Inc. v. Mylan Inc. et al.*, Civil Action No. 2:10-cv-06018 (Mylan Inc., Mylan Pharmaceuticals); *Schering Corporation et al. v. Mylan Pharmaceuticals Inc. et al.*, Civil Action No. 2:10-cv-03085 (Mylan Pharmaceuticals); *Hoffman-La Roche Inc. v. Mylan Inc. et al.*, Civil Action No. 09-cv-1692 (Mylan Inc., Mylan Pharmaceuticals); *Warner Chilcott Company, LLC v. Impax Laboratories, Inc. et al.*, Civil Action No. 08-cv-6034 (Mylan Pharmaceuticals, Mylan Inc.).

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that to conserve the resources of the parties and the Court, and under the particular circumstances surrounding those actions, MPI, MLL, and/or Mylan Inc. did not contest venue for the limited purposes of Civil Action Nos. 3:15-cv-3392, 3:12-cv-01378, 2:10-cv-06018, 2:10-cv-03085, and 09-cv-1692 only. Defendants deny any remaining allegations in paragraph 20. Defendants further deny that venue is proper in the District of New Jersey.

THE PATENTS IN SUIT

21. The PTO issued the '096 patent on June 6, 2017. The '096 patent claims, *inter alia*, pharmaceutical preparations of methylnaltrexone. Plaintiffs hold all substantial rights in the '096 patent and have the right to sue for infringement thereof. A copy of the '096 patent is attached hereto as Exhibit A.

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Plaintiffs purport to attach a copy of the '096 patent to the Amended Complaint as Exhibit A. Defendants further admit that the face of the '096 patent indicates that it issued on June 6, 2017 and that Progenics Pharmaceuticals, Inc. ("Progenics") is the purported assignee of the '096 patent. Defendants deny any remaining allegations in paragraph 21, including any suggestion or implication that the '096 patent was duly and legally issued or is valid or enforceable.

22. The PTO issued the '445 patent on November 15, 2016. The '445 patent claims, *inter alia*, compositions of methylnaltrexone and methods of using the same. Plaintiffs hold all substantial rights in the '445 patent and have the right to sue for infringement thereof. A copy of the '445 patent is attached hereto as Exhibit B.

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Plaintiffs purport to attach a copy of the '445 patent to the Amended Complaint as Exhibit B. Defendants further admit that the face of the '445 patent indicates that it issued on November 15, 2016 and that Wyeth LLC is the purported assignee of the '445 patent. Defendants deny any remaining allegations in paragraph 22, including any suggestion or implication that the '445 patent was duly and legally issued or is valid or enforceable.

23. Salix is the holder of New Drug Application ("NDA") No. 021964 for subcutaneous Relistor®. In conjunction with NDA No. 021964, the '096 and '445 patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book"), together with U.S. Patent Nos. 8,247,425, 8,420,663, 8,552,025, 8,822,490, and 9,180,125, which are the subject of an on-going infringement litigation in the District of New Jersey: *Valeant*

Pharmaceuticals et al. v. Mylan Pharmaceuticals Inc., et al., Civil Action No. 2:15-cv-08180 (consolidated).

ANSWER: Upon information and belief, Defendants admit that FDA public records indicate that Salix is the holder of NDA No. 021964 for methylnaltrexone bromide injection, for subcutaneous use, 8 mg/0.4 mL and 12 mg/0.6 mL single-dose pre-filled syringes and 12 mg/0.6 mL single-dose vial, which are marketed under the trade name Relistor®. Upon information and belief, Defendants further admit that FDA's publication titled *Approved Drug Products and Therapeutic Equivalence Evaluations* (the "Orange Book") identifies, *inter alia*, the '096 patent, the '445 patent, and U.S. Patent Nos. 8,247,425, 8,420,663, 8,552,025, 8,822,490, and 9,180,125 as purportedly associated with NDA No. 021964. Defendants further admit that Plaintiffs brought the actions styled *Valeant Pharmaceuticals et al. v. Mylan Pharmaceuticals Inc., et al.*, Civil Action Nos. 2:15-08180 and 2:16-00035 against Defendants in the District of New Jersey, and that Plaintiffs' complaints in those actions purport to state claims of infringement against Defendants with respect to U.S. Patent Nos. 8,247,425, 8,420,663, 8,552,025, 8,822,490, and 9,180,125. Defendants further admit that Civil Action Nos. 2:15-08180 and 2:16-00035 are consolidated for all purposes under the case caption Civil Action No. 2:15-08180(SRC)(CLW) (consolidated). Defendants deny that Plaintiffs' claims of infringement in Civil Action No. 2:15-08180(SRC)(CLW) (consolidated) are proper and/or have any merit. Defendants deny any remaining allegations in Paragraph 23.

24. Methylnaltrexone bromide formulations for subcutaneous injection, 12 mg/0.6 mL single-use vial, and 8 mg/0.4 mL and 12 mg/0.6 mL pre-filled syringes are sold in the United States under the trademark Relistor®.

ANSWER: Upon information and belief, Defendants admit that at least the products that are the subject of NDA No. 021964 are marketed in the United States under the trade name

Relistor®. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 24, and therefore deny them.

ALLEGATIONS OF MYLAN'S INFRINGING ANDA NO. 208592 SUBMISSION

25. Upon information and belief, Mylan filed or caused to be filed with the FDA ANDA No. 208592, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

ANSWER: Defendants admit that MLL, as the sole applicant, submitted to FDA ANDA No. 208592. Defendants deny any remaining allegations in paragraph 25.

26. Upon information and belief, Mylan's ANDA No. 208592 seeks FDA approval to sell in the United States Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection, 12 mg/0.6 mL single-use vial, intended to be a generic version of Relistor® 12 mg/0.6 mL single-use vials.

ANSWER: Defendants admit that MLL submitted to FDA ANDA No. 208592 seeking FDA approval for its proposed methylnaltrexone bromide injection, for subcutaneous use, 12 mg/0.6 mL single-dose vial. Defendants deny any remaining allegations in paragraph 26.

27. Salix, Progenics and Wyeth received a letter from Mylan Pharmaceuticals dated July 19, 2017, purporting to be a Notice of Certification for ANDA No. 208592 ("Mylan's ANDA No. 208592 notice letter") under Section 505(j)(2)(B)(iv) of the Act, 21 U.S.C. § 355(j)(2)(B)(iv), and 21 C.F.R. § 314.95. Mylan's ANDA No. 208592 notice letter was addressed to Wyeth at Madison, New Jersey.

ANSWER: Defendants admit that on July 19, 2017, a letter styled Notice of Paragraph IV Certification regarding the '096 patent pursuant to Section 505(j)(2)(B)(iv) of the U.S. Federal Food, Drug, and Cosmetic Act (the "Act") and 21 C.F.R. § 314.95 for ANDA No. 208592 was sent to Wyeth/Wyeth LLC, Progenics, and Salix ("July 19, 2017 Notice Letter for ANDA No. 208592"). On information and belief, Defendants admit that records indicate that Wyeth/Wyeth LLC, Progenics, and Salix received the July 19, 2017 Notice Letter for ANDA No. 208592. Defendants state that the July 19, 2017 Notice Letter for ANDA No. 208592 speaks for itself, and Defendants deny the allegations of paragraph 27 to the extent they deviate from or otherwise do

not accurately reflect or describe the July 19, 2017 Notice Letter for ANDA No. 208592. Defendants deny any remaining allegations in paragraph 27.

28. Mylan's ANDA No. 208592 notice letter states that "Mylan Pharmaceuticals Inc. is the authorized U.S. contact for applicant Mylan Laboratories Limited . . . with respect to ANDA No. 208-592 and related ANDA No. 208-594." Mylan's notice letter refers to Mylan Pharmaceuticals and Mylan Labs collectively as "Mylan."

ANSWER: Defendants state that the July 19, 2017 Notice Letter for ANDA No. 208592 speaks for itself, and Defendants deny the allegations of paragraph 28 to the extent they deviate from or otherwise do not accurately reflect or describe the July 19, 2017 Notice Letter for ANDA No. 208592. Defendants deny any remaining allegations in paragraph 28.

29. Mylan's ANDA No. 208592 notice letter alleges that Mylan has submitted to the FDA ANDA No. 208592 seeking FDA approval to sell Mylan's generic methylnaltrexone vial product, intended to be a generic version of Relistor® 12 mg/0.6 mL single-use vials.

ANSWER: Defendants admit that the July 19, 2017 Notice Letter for ANDA No. 208592 indicates that MLL, as the sole applicant, submitted to FDA ANDA No. 208592 seeking FDA approval for its proposed methylnaltrexone bromide injection, for subcutaneous use, 12 mg/0.6 mL single-dose vial. Defendants state that the July 19, 2017 Notice Letter for ANDA No. 208592 speaks for itself, and Defendants deny the allegations of paragraph 29 to the extent they deviate from or otherwise do not accurately reflect or describe the July 19, 2017 Notice Letter for ANDA No. 208592. Defendants deny any remaining allegations in paragraph 29.

30. Mylan's ANDA No. 208592 notice letter states that the "FDA received Mylan's ANDA, which contained the required bioavailability or bioequivalence data or information" for Mylan's generic methylnaltrexone vial product and Relistor® 12 mg/0.6 mL single-use vials.

ANSWER: Paragraph 30 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants state that the July 19, 2017 Notice Letter for ANDA No. 208592 speaks for itself, and Defendants deny the allegations of paragraph 30 to the extent

they deviate from or otherwise do not accurately reflect or describe the July 19, 2017 Notice Letter for ANDA No. 208592. Defendants deny any remaining allegations in paragraph 30.

31. Mylan's ANDA No. 208592 notice letter, which is required by statute and regulation to provide a full and detailed explanation regarding any non-infringement defenses, does not allege non-infringement of any claim of the '096 patent.

ANSWER: Paragraph 31 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

32. The '445 patent is listed in the Orange Book in conjunction with NDA No. 021964 for subcutaneous Relistor®.

ANSWER: Upon information and belief, Defendants admit that FDA's Orange Book identifies, *inter alia*, the '445 patent as purportedly associated with NDA No. 021964. Defendants state that on September 21, 2017, a letter styled Notice of Paragraph IV Certification regarding the '445 patent pursuant to Section 505(j)(2)(B)(iv) of the Act and 21 C.F.R. § 314.95 for ANDA No. 208592 was sent to Wyeth/Wyeth LLC, Progenics, and Salix ("September 21, 2017 Notice Letter for ANDA No. 208592"). Defendants further state that, on information and belief, records indicate that the September 21, 2017 Notice Letter for ANDA No. 208592 was received by Wyeth/Wyeth LLC, Progenics, and Salix. Defendants deny any remaining allegations in paragraph 32.

33. Upon information and belief, ANDA No. 208592 seeks approval of Mylan's generic methylnaltrexone vial product that is the same, or substantially the same, as Relistor® 12 mg/0.6 mL single-use vials.

ANSWER: Paragraph 33 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that MLL submitted to FDA ANDA No. 208592 seeking approval for its proposed methylnaltrexone bromide injection, for subcutaneous use, 12 mg/0.6 mL single-dose vial. Defendants deny any remaining allegations in paragraph 33.

34. Upon information and belief, Mylan Pharmaceuticals' actions relating to ANDA No. 208592 complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of Mylan Inc. and Mylan Labs.

ANSWER: Denied.

ALLEGATIONS OF MYLAN'S INFRINGING ANDA NO. 208594 SUBMISSION

35. Upon information and belief, Mylan filed or caused to be filed with the FDA ANDA No. 208594, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

ANSWER: Defendants admit that MLL, as the sole applicant, submitted to FDA ANDA No. 208594. Defendants deny any remaining allegations in paragraph 35.

36. Upon information and belief, Mylan's ANDA No. 208594 seeks FDA approval to sell in the United States Mylan's generic methylnaltrexone bromide for subcutaneous injection, 8 mg/0.4 mL and 12 mg/0.6 mL pre-filled syringes, intended to be a generic version of Relistor® 8 mg/0.4 mL and 12 mg/0.6 mL pre-filled syringes.

ANSWER: Defendants admit that MLL submitted to FDA ANDA No. 208594 seeking FDA approval for its proposed methylnaltrexone bromide injection, for subcutaneous use, 8 mg/0.4 mL and 12 mg/0.6 mL single-dose pre-filled syringes. Defendants deny any remaining allegations in paragraph 36.

37. Salix, Progenics and Wyeth received a letter from Mylan Pharmaceuticals dated July 19, 2017, purporting to be a Notice of Certification for ANDA No. 208594 ("Mylan's ANDA No. 208594 notice letter") Section 505(j)(2)(B)(iv) of the Act, 21 U.S.C. § 355(j)(2)(B)(iv), and 21 C.F.R. § 314.95. Mylan's ANDA No. 208594 notice letter was addressed to Wyeth at Madison, New Jersey.

ANSWER: Defendants admit that on July 19, 2017, a letter styled Notice of Paragraph IV Certification regarding the '096 patent pursuant to Section 505(j)(2)(B)(iv) of the Act and 21 C.F.R. § 314.95 for ANDA No. 208594 was sent to Wyeth/Wyeth LLC, Progenics, and Salix ("July 19, 2017 Notice Letter for ANDA No. 208594"). On information and belief, Defendants admit that records indicate that Wyeth/Wyeth LLC, Progenics, and Salix received the July 19, 2017 Notice Letter for ANDA No. 208594. Defendants state that the July 19, 2017 Notice Letter

for ANDA No. 208594 speaks for itself, and Defendants deny the allegations of paragraph 37 to the extent they deviate from or otherwise do not accurately reflect or describe the July 19, 2017 Notice Letter for ANDA No. 208594. Defendants deny any remaining allegations in paragraph 37.

38. Mylan's ANDA No. 208594 notice letter states that "Mylan Pharmaceuticals Inc. is the authorized U.S. contact for applicant Mylan Laboratories Limited . . . with respect to ANDA No. 208-594 and related ANDA No. 208-592." Mylan's ANDA No. 208594 notice letter refers to Mylan Pharmaceuticals and Mylan Labs collectively as "Mylan."

ANSWER: Defendants state that the July 19, 2017 Notice Letter for ANDA No. 208594 speaks for itself, and Defendants deny the allegations of paragraph 38 to the extent they deviate from or otherwise do not accurately reflect or describe the July 19, 2017 Notice Letter for ANDA No. 208594. Defendants deny any remaining allegations in paragraph 38.

39. Mylan's ANDA No. 208594 notice letter alleges that Mylan has submitted to the FDA ANDA No. 208594 seeking FDA approval to sell Mylan's generic methylnaltrexone pre-filled syringe products, intended to be generic versions of Relistor® 8 mg/0.4 mL and 12 mg/0.6 mL pre-filled syringes.

ANSWER: Defendants admit that the July 19, 2017 Notice Letter for ANDA No. 208594 indicates that MLL, as the sole applicant, submitted to FDA ANDA No. 208594 seeking FDA approval for its proposed methylnaltrexone bromide injection, for subcutaneous use, 8 mg/0.4 mL and 12 mg/0.6 mL single-dose pre-filled syringes. Defendants state that the July 19, 2017 Notice Letter for ANDA No. 208594 speaks for itself, and Defendants deny the allegations of paragraph 39 to the extent they deviate from or otherwise do not accurately reflect or describe the July 19, 2017 Notice Letter for ANDA No. 208594. Defendants deny any remaining allegations in paragraph 39.

40. Mylan's ANDA No. 208594 notice letter states that the "FDA received Mylan's ANDA, which contained the required bioavailability or bioequivalence data or information" for

Mylan's generic methylnaltrexone pre-filled syringe products and Relistor® 8 mg/0.4 mL and 12 mg/0.6 mL single-use pre-filled syringes.

ANSWER: Paragraph 40 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants state that the July 19, 2017 Notice Letter for ANDA No. 208594 speaks for itself, and Defendants deny the allegations of paragraph 40 to the extent they deviate from or otherwise do not accurately reflect or describe the July 19, 2017 Notice Letter for ANDA No. 208594. Defendants deny any remaining allegations in paragraph 40.

41. Mylan's ANDA No. 208594 notice letter, which is required by statute and regulation to provide a full and detailed explanation regarding any non-infringement defenses, does not allege non-infringement of any claim of the '096 patent.

ANSWER: Paragraph 41 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

42. The '445 patent is listed in the Orange Book in conjunction with NDA No. 021964 for subcutaneous Relistor®.

ANSWER: Upon information and belief, Defendants admit that FDA's Orange Book identifies, *inter alia*, the '445 patent as purportedly associated with NDA No. 021964. Defendants state that on September 21, 2017, a letter styled Notice of Paragraph IV Certification regarding the '445 patent pursuant to Section 505(j)(2)(B)(iv) of the Act and 21 C.F.R. § 314.95 for ANDA No. 208594 was sent to Wyeth/Wyeth LLC, Progenics, and Salix ("September 21, 2017 Notice Letter for ANDA No. 208594"). Defendants further state that, on information and belief, records indicate that the September 21, 2017 Notice Letter for ANDA No. 208594 was received by Wyeth/Wyeth LLC, Progenics, and Salix. Defendants deny any remaining allegations in paragraph 42.

43. Upon information and belief, ANDA No. 208594 seeks approval of Mylan's generic methylnaltrexone pre-filled syringe products that are the same, or substantially the same, as Relistor® 8 mg/0.4 mL and 12 mg/0.6 mL pre-filled syringes.

ANSWER: Paragraph 43 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that MLL submitted to FDA ANDA No.

208594 seeking approval for its proposed methylnaltrexone bromide injection, for subcutaneous use, 8 mg/0.4 mL and 12 mg/0.6 mL single-dose pre-filled syringes. Defendants deny any remaining allegations in paragraph 43.

44. Upon information and belief, Mylan Pharmaceuticals' actions relating to ANDA No. 208594 complained of herein were done with the cooperation, the participation, the assistance of, and at least in art for the benefit of Mylan Inc. and Mylan Labs.

ANSWER: Denied.

COUNT I AGAINST MYLAN

Alleged Infringement of the '096 Patent under § 271(e)(2) (ANDA No. 208592)

45. Paragraphs 1-44 are incorporated herein as set forth above.

ANSWER: Defendants reassert and incorporate by reference their responses to paragraphs 1–44 in full herein.

46. Under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '096 patent by submitting, or causing to be submitted to the FDA, ANDA No. 208592 seeking approval for the commercial marketing of Mylan's generic methylnaltrexone vial product before the expiration date of the '096 patent.

ANSWER: Defendants admit that MLL submitted to FDA ANDA No. 208592 seeking approval for its proposed methylnaltrexone bromide injection, for subcutaneous use, 12 mg/0.6 mL single-dose vial, prior to the expiration of, *inter alia*, the '096 patent. Defendants deny any remaining allegations in paragraph 46.

47. Upon information and belief, Mylan's generic methylnaltrexone vial product will, if approved and marketed, infringe at least one claim of the '096 patent.

ANSWER: Denied.

48. Upon information and belief, Mylan will, through the manufacture, use, import, offer for sale, and/or sale of Mylan's generic methylnaltrexone vial product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '096 patent.

ANSWER: Denied.

COUNT II AGAINST MYLAN

Alleged Declaratory Judgment of Infringement of the '096 Patent (ANDA No. 208592)

49. Paragraphs 1-48 are incorporated herein as set forth above.

ANSWER: Defendants reassert and incorporate by reference their responses to paragraphs 1–48 in full herein.

50. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: Paragraph 50 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

51. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

ANSWER: Paragraph 51 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

52. Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Mylan's generic methylnaltrexone vial product before the expiration date of the '096 patent, including Mylan's filing of ANDA No. 208592.

ANSWER: Denied.

53. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic methylnaltrexone vial product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '096 patent.

ANSWER: Denied.

54. Plaintiffs are entitled to declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic methylnaltrexone vial product will constitute infringement of at least one claim of the '096 patent.

ANSWER: Denied.

COUNT III AGAINST MYLAN

Alleged Infringement of the '096 Patent under § 271(e)(2) (ANDA No. 208594)

55. Paragraphs 1-54 are incorporated herein as set forth above.

ANSWER: Defendants reassert and incorporate by reference their responses to paragraphs 1–54 in full herein.

56. Under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '096 patent by submitting, or causing to be submitted to the FDA, ANDA No. 208594 seeking approval for the commercial marketing of Mylan's generic methylnaltrexone pre-filled syringe products before the expiration date of the '096 patent.

ANSWER: Defendants admit that MLL submitted to FDA ANDA No. 208594 seeking approval for its proposed methylnaltrexone bromide injection, for subcutaneous use, 8 mg/0.4 mL and 12 mg/0.6 mL single-dose pre-filled syringes, prior to the expiration of, *inter alia*, the '096 patent. Defendants deny any remaining allegations in paragraph 56.

57. Upon information and belief, Mylan's generic methylnaltrexone pre-filled syringe products will, if approved and marketed, infringe at least one claim of the '096 patent.

ANSWER: Denied.

58. Upon information and belief, Mylan will, through the manufacture, use, import, offer for sale, and/or sale of Mylan's generic methylnaltrexone pre-filled syringe products, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '096 patent.

ANSWER: Denied.

COUNT IV AGAINST MYLAN

Alleged Declaratory Judgment of Infringement of the '096 Patent (ANDA No. 208594)

59. Paragraphs 1-58 are incorporated herein as set forth above.

ANSWER: Defendants reassert and incorporate by reference their responses to paragraphs 1–58 in full herein.

60. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: Paragraph 60 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

61. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

ANSWER: Paragraph 61 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

62. Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Mylan's generic methylnaltrexone pre-filled syringe products before the expiration date of the '096 patent, including Mylan's filing of ANDA No. 208594.

ANSWER: Denied.

63. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic methylnaltrexone pre-filled syringe products will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '096 patent.

ANSWER: Denied.

64. Plaintiffs are entitled to declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic methylnaltrexone pre-filled syringe products will constitute infringement of at least one claim of the '096 patent.

ANSWER: Denied.

COUNT V AGAINST MYLAN

Alleged Infringement of the '445 Patent under § 271(e)(2) (ANDA No. 208592)

65. Paragraphs 1-64 are incorporated herein as set forth above.

ANSWER: Defendants reassert and incorporate by reference their responses to paragraphs 1–64 in full herein.

66. Under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '445 patent by submitting, or causing to be submitted to the FDA, ANDA No. 208592 seeking approval

for the commercial marketing of Mylan's generic methylnaltrexone vial product before the expiration date of the '445 patent.

ANSWER: Defendants admit that MLL submitted to FDA ANDA No. 208592 seeking approval for its proposed methylnaltrexone bromide injection, for subcutaneous use, 12 mg/0.6 mL single-dose vial, prior to the expiration of, *inter alia*, the '445 patent. Defendants deny any remaining allegations in paragraph 66.

67. Upon information and belief, Mylan's generic methylnaltrexone vial product will, if approved and marketed, infringe at least one claim of the '445 patent.

ANSWER: Denied.

68. Upon information and belief, Mylan will, through the manufacture, use, import, offer for sale, and/or sale of Mylan's generic methylnaltrexone vial product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '445 patent.

ANSWER: Denied.

COUNT VI AGAINST MYLAN

Alleged Declaratory Judgment of Infringement of the '445 Patent (ANDA No. 208592)

69. Paragraphs 1-68 are incorporated herein as set forth above.

ANSWER: Defendants reassert and incorporate by reference their responses to paragraphs 1–68 in full herein.

70. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: Paragraph 70 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

71. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

ANSWER: Paragraph 71 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

72. Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Mylan's generic methylnaltrexone vial product before the expiration date of the '445 patent, including Mylan's filing of ANDA No. 208592.

ANSWER: Denied.

73. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic methylnaltrexone vial product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '445 patent.

ANSWER: Denied.

74. Plaintiffs are entitled to declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic methylnaltrexone vial product will constitute infringement of at least one claim of the '445 patent.

ANSWER: Denied.

COUNT VII AGAINST MYLAN

Alleged Infringement of the '445 Patent under § 271(e)(2) (ANDA No. 208594)

75. Paragraphs 1-74 are incorporated herein as set forth above.

ANSWER: Defendants reassert and incorporate by reference their responses to paragraphs 1–74 in full herein.

76. Under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '445 patent by submitting, or causing to be submitted to the FDA, ANDA No. 208594 seeking approval for the commercial marketing of Mylan's generic methylnaltrexone pre-filled syringe products before the expiration date of the '445 patent.

ANSWER: Defendants admit that MLL submitted to FDA ANDA No. 208594 seeking approval for its proposed methylnaltrexone bromide injection, for subcutaneous use, 8 mg/0.4 mL and 12 mg/0.6 mL single-dose pre-filled syringes, prior to the expiration of, *inter alia*, the '445 patent. Defendants deny any remaining allegations in paragraph 76.

77. Upon information and belief, Mylan's generic methylnaltrexone pre-filled syringe products will, if approved and marketed, infringe at least one claim of the '445 patent.

ANSWER: Denied.

78. Upon information and belief, Mylan will, through the manufacture, use, import, offer for sale, and/or sale of Mylan's generic methylnaltrexone pre-filled syringe products, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '445 patent.

ANSWER: Denied.

COUNT IV [sic] AGAINST MYLAN

Alleged Declaratory Judgment of Infringement of the '445 Patent (ANDA No. 208594)

79. Paragraphs 1-78 are incorporated herein as set forth above.

ANSWER: Defendants reassert and incorporate by reference their responses to paragraphs 1–78 in full herein.

80. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: Paragraph 80 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

81. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

ANSWER: Paragraph 81 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

82. Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Mylan's generic methylnaltrexone pre-filled syringe products before the expiration date of the '445 patent, including Mylan's filing of ANDA No. 208594.

ANSWER: Denied.

83. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic methylnaltrexone pre-filled syringe products will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '445 patent.

ANSWER: Denied.

84. Plaintiffs are entitled to declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic methylnaltrexone pre-filled syringe products will constitute infringement of at least one claim of the '445 patent.

ANSWER: Denied.

RESPONSE TO PLAINTIFFS' REQUESTED RELIEF

Defendants deny that Plaintiffs are entitled to any of the relief requested in paragraphs 1–12 of the Amended Complaint's Prayer for Relief, or otherwise.

DEFENDANTS' SEPARATE DEFENSES

Without prejudice to the denials set forth in their Answer, without admitting any allegations of the Amended Complaint not expressly admitted, and without assuming the burden of proof on any such defense that would otherwise rest with Plaintiffs, Defendants assert the following separate defenses to the Amended Complaint:

First Separate Defense

Defendants do not, have not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '096 and '445 patents, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of the products that are the subject of MLL's ANDA Nos. 208592 and 208594 do not, have not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '096 and '445 patents, either directly, indirectly, contributorily, by inducement, or in any other manner.

Second Separate Defense

The claims of the '096 and '445 patents are invalid and/or unenforceable for failure to comply with and/or satisfy one or more of the conditions and requirements of Title 35 of the United States Code, including, but not limited to, one or more of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b).

Third Separate Defense

The Amended Complaint, in whole or in part, fails to state a claim upon which relief can be granted.

Fourth Separate Defense

Defendants are not subject to personal jurisdiction in the District of New Jersey. Plaintiffs do not and cannot establish that sufficient grounds exist, under the applicable constitutional standards or long-arm statute, for this Court to exercise personal jurisdiction over Defendants in this action.

Fifth Separate Defense

Venue is improper in the District of New Jersey.

Sixth Separate Defense

Any purported claim against Defendants in the Amended Complaint for infringement under 35 U.S.C. §§ 271(a), (b), (c), and/or (g) should be dismissed for lack of subject matter jurisdiction because, at present, there is no real and immediate case or controversy under those provisions.

Seventh Separate Defense

The Complaint fails to state a cause of action under 35 U.S.C. §§ 271(a), (b), (c), and/or (g) against Defendants because Plaintiffs have not pleaded with particularity facts regarding any post-ANDA approval activities.

Eighth Separate Defense

Plaintiffs are barred by 35 U.S.C. § 288 from recovering any costs associated with this suit.

Reservation of Rights

Defendants expressly reserve the right to supplement and/or amend their Answer to Plaintiffs' Amended Complaint, including, but not limited to, supplementation and/or amendment of their defenses and amplifications of denials, as additional facts and information become known through the course of this case and discovery.

Dated: December 22, 2017

Respectfully submitted,

By: s/ Amy Luria

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